IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAYER INTELLECTUAL PROPERTY GMBH and BAYER PHARMA AG, Plaintiffs, v. WARNER CHILCOTT COMPANY, LLC, WARNER CHILCOTT (US), LLC, and WARNER CHILCOTT PLC, Defendants.	)	Civil Action No. 12-1032-GMS

ORDER CONSTRUING THE TERMS OF U.S. PATENT NO. 5,980,940

After having considered the submissions of the parties, and hearing oral argument on the matter, IT IS HEREBY ORDERED, ADJUDGED, and DECREED that, as used in the asserted claims of U.S. Patent No. 5,980,940 ("the '940 patent"):

1. The parties have agreed that the term "**between these two hormone components**" means "immediately after a hormone component containing a combination of estrogen and progestin, and immediately before a hormone component containing estrogen only."

At the conclusion of the Markman hearing, Bayer stated that it was not seeking literal infringement, and agreed to adopt Warner Chilcott's proposed construction. (D.I. 84, Transcript of July 14, 2014 hearing ("Tr."), at 79:5-80:1.)

2. The term "**effective estrogen content**" is construed to mean "daily dose of estrogen equivalent to no more than 40 μg of ethinyl estradiol."

The court adopts Bayer's proposal. The disputed term appears in independent claim 1. The specification and dependent claims list a number of different estrogens that may be used in the claimed oral-contraceptive regimen. Bayer argues, and the court agrees, that "effective

estrogen content" therefore refers to the amount of a particular type of estrogen in either the combined pill or the unopposed estrogen pill. (D.I. 61 at 4-5.) And because ethinyl estradiol is the estrogen in the accused product, both parties seek a construction that relates the disputed term to the estrogen at issue. As such, the parties' dispute is whether the court should construe the term with reference to the lowest or highest level of ethinyl estradiol contained in the dependent claims and specification.

Warner Chilcott's proposed construction is founded on the lowest level disclosed in a preferred embodiment, and requires ethinyl estradiol in an amount of at least 15 μg in the combined pill and at least 2 μg in the unopposed pill. Warner Chilcott contends that, given the patent's objective to provide a daily estrogen content that was "as low as possible in each individual dosage unit," the inventors would have preferred and described lower respective doses if they believed that such estrogen content would be "effective." (D.I. 62 at 17.) The court disagrees. "[T]he subjective intent of the inventor when he used a particular term is of little or no probative weight in determining the scope of a claim." *Howmedica Osteonics Corp. v. Wright Med. Tech., Inc.*, 540 F.3d 1337, 1346 (Fed. Cir. 2008). In addition, "when a claim term is expressed in general descriptive words, [the court] will not ordinarily limit the term to a numerical range that may appear in the written description or in other claims." *Conoco, Inc. v. Energy & Envtl. Int'l, L.C.*, 460 F.3d 1349, 1358 (Fed. Cir. 2006) (citation omitted). Indeed, the specification provides another embodiment that does not recite any limits on the amount of ethinyl estradiol, ('940 patent, 4:36-57), and the intrinsic record does not disavow claim scope. Therefore, the court finds that the term "effective estrogen content" in claim 1 captures pharmaceutical combinations with ethinyl estradiol levels below 15 μg in the combined pill and below 2 μg in the unopposed pill.

3. The court is unable to construe the disputed phrase "**high contraceptive reliability, low incidence of follicular development, and satisfactory cycle control, with reliable avoidance of intracyclic menstrual bleeding and undesirable side-effects**."

The court agrees with Warner Chilcott that the disputed phrase should not be construed as a single term because it includes five distinct requirements that cover different oral contraceptive concepts/characteristics. (*See* D.I. 62 at 1-2; '940 patent, 1:51-59 (distinguishing contraceptive reliability, cycle control, and side effects); *id.*, 6:9-27 (distinguishing follicular development, contraceptive reliability, cycle control, and side effects).) And while the characteristics may be interrelated as Bayer argues, (D.I. 61 at 1), the court's construction for an infringement analysis must include objective measures for each individual characteristic.[1] *See Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (stating court's purpose in claim construction is to provide "meaning and scope of the claims asserted to be infringed").

"The words of a claim are generally given their ordinary and customary meaning as understood by a person of ordinary skill in the art when read in the context of the specification and prosecution history." *Thorner v. Sony Computer Entm't Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012). The terms at issue, however, include subjective words, such as, "high," low," "satisfactory," and "reliable," that lack clarity and fail to identify the claim scope. "When a word of degree is used the district court must determine whether the patent's specification provides some standard for measuring that degree." *Datamize, LLC v. Plumtree Software, Inc.*, 417 F.3d 1342, 1351 (Fed. Cir. 2005). To resolve that problem, Warner Chilcott argues that the claimed regimen must be superior to all prior art cited in the patent for every characteristic listed in the disputed phrase because the inventors disavowed claim scope in the specification and during

[1] Bayer contends that the phrase describes a combination of effects that results in a "profile," (D.I. 61 at 7-9), but its proposed construction does not provide the court with any guidance as to how an infringement analysis would proceed against the combined effects.

prosecution. (D.I. 62 at 1-2.) Bayer, on the other hand, argues that the court's construction should compare each characteristic to "a population of healthy women not using hormonal birth control." (D.I. 61 at 7.) The court finds that the intrinsic record does not support either party's proposal.

The disputed phrase was added to the claims to overcome an obvious rejection based on a combination of two prior art references. (D.I. 71-8, Ex. 4 at 2; '940 patent, 7:35-39). In the rejection response, the inventors distinguished their low-dose oral contraceptive regimen from the cited prior art and other regimens described in the specification:

> [t]he claimed invention is a biphasic regimen of very low dosage hormonal agents, comprising a first combination of a low dosage of an estrogen and a gestagen, followed by a placebo or pill-free period, and a second agent comprising a low dose of an estrogen. The deficiencies of the prior art multiphasic combination preparations . . . are discussed in the specification . . . and contrasted with the superior results of the present regimen, in particular that it provides a contraceptive effect whereby the low effective estrogen content and low total hormone content provides high contraceptive reliability, low incidence of follicular development, and satisfactory cycle control, with reliable avoidance of intracyclic menstrual bleeding and undesirable side-effects. There is no suggestion in either of the references that these results could be achieved in low dose regimens using the claimed combination preparation.

(D.I. 71-8, Ex.4 at 5.)

The specification contains two discussions regarding the "deficiencies of the prior art." The first concerns a prior art regime, Mercilon, containing 20 μg of ethinyl estradiol that resulted in some follicular development and had cycle control that was "less good than . . . preparations with a higher estrogen dose." ('940 patent, 2:55-61.) The second discusses prior-art regimens with 21 days of combined progestin-estrogen pills followed by seven days of exclusively estrogen pills and how those regimens may result in follicular development that jeopardizes

contraceptive protection. (*Id.*, 3:18-39.) Neither of those statements satisfies the high standard for claim disavowal. *See Teleflex, Inc. v. Ficosa North America Corp.*, 299 F.3d 1313, 1327 (Fed. Cir. 2002) (stating a patentee may demonstrate "an intent to deviate from the ordinary and accustomed meaning of a claim term by redefining the term or by characterizing the invention in the intrinsic record using words or expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope."). Indeed, the specification does not state that the prior art Mercilon regime had a "high" incidence of follicular development or "unsatisfactory" cycle control, and it does not discuss any of the other claim limitations -- contraceptive reliability, side effects, or incidence of intracyclic menstrual bleeding. Similarly, the specification does not state that the other described prior art regimes had a "high" incidence of follicular development or "low" contraceptive reliability, and it is silent regarding those regimes' side effects, cycle control, and incidences of intracyclic menstrual bleeding. Therefore, the court finds that the specification does not contain "words or expressions of manifest exclusion or restriction" that indicate the inventors intended to disavow the described prior-art regimes from the scope of the characteristics set out in the disputed phrase. *See Teleflex*, 299 F.3d at 1327.

Likewise, the specification's discussion of "superior results" does not amount to disavowal of claim scope. The specification states that the claimed regimen has "advantages . . . compared to the previously described preparations, especially those with a daily ethinyl estradiol dose of less than 30 μg and those with a prolonged pill-free interval." ('940 patent, 6:9-14). The identified "advantages" include "[a] significantly lower frequency of follicular development," "greater contraceptive reliability," "a lower incidence of side effects," "considerably improved cycle control," and in particular, "better cycle control, specifically from the first intake cycle." (*Id.* at 6:15-39.) The specification does not, however, state that the prior-art regimes have low

contraceptive reliability, high incidences of follicular development, unsatisfactory cycle control, with unreliable avoidance of intracyclic menstrual bleeding and undesirable side effects.

Finally, the court disagrees with Warner Chilcott's assertion that the inventors disavowed claim scope during prosecution by claiming to have achieved each of the characteristics in the disputed phrase "for the first time." In a rejection response, the inventors explained that:

> [t]here is no teaching in the cited prior art that an estrogen could be administered in low effective amounts by the claimed regimen, wherein each individual dosage unit has a very low effective estrogen content and a very low effective total hormone content per administration cycle, and whereby the low effective estrogen content and low total hormone content provides high contraceptive reliability, low incidence of follicular development, and satisfactory cycle control, with reliable avoidance of intracyclic menstrual bleeding and undesirable side-effects. The present invention provided such a low-dose, contraceptively effective pharmaceutical combination preparation for the first time.

(D.I. 71-8, Ex.4 at 5.) Read in its entirety, the court finds that the statements do not satisfy the high standard for disavowal of claim scope. *See Omega Eng'g Inc. v. Raytek Corp.*, 334 F.3d 1314, 1325 (Fed. Cir. 2003) (holding that the doctrine of prosecution disclaimer only applies where "the alleged disavowing statements [are] both so clear as to show reasonable clarity and deliberateness, and so unmistakable as to be unambiguous evidence of disclaimer."). The inventors did not claim to have achieved any of the particular characteristics for the first time; rather, they explained that the novel aspect of the claimed regimen is that it provides desirable oral contraceptive characteristics while using both low estrogen and low total hormonal amounts. As such, the inventors did not disavow the results achieved by prior art regimes, nor did they claim to have achieved any particular characteristic "for the first time." Therefore, the court finds that the intrinsic record does not support Warner Chilcott's proposal requiring the claimed regimen to be superior to all prior art described in the specification for each characteristic in the

disputed phrase, ie., the highest contraceptive reliability, best cycle control, and the lowest incidences of follicular development, intracyclic menstrual bleeding, and side effects.

Likewise, the court is not convinced that the intrinsic record supports Bayer's proposal to construe each term "as compared to a population of healthy women not using hormonal birth control." As an initial matter, Warner Chilcott is correct that "neither the specification nor the prosecution history anywhere mentions 'a population of healthy women not using hormonal birth control,' let alone suggests using such a population is an objective standard against which to assess the meaning of the relative, subjective terms in the claims." (D.I. 69 at 3.) The court also agrees with Warner Chilcott that Bayer's proposed construction would add greater ambiguity to the scope of the claims. Bayer's proposal does not indicate who the population of women consists of, and how the "contraceptive reliability," "follicular development," "cycle control," and "side effects" must compare to the "population of healthy women" for an oral contraceptive to satisfy the claim limitations. The court, therefore, is not convinced by Bayer's argument that each term within the disputed phrase has a known meaning in the art that supports comparisons to "a population of healthy women not using hormonal earth control." (*See* D.I. 67 at 4-16.)

After rejecting the party's proposals, the court is left at an impasse and is unable to discern the meets and bounds of the asserted claims. The plain meaning of the claim language leaves the court with numerous questions, the answers to which are necessary to complete an infringement analysis regarding when the claim limitations are met. For example, how high must the contraceptive reliability be? What incidence of follicular development would be considered low? What constitutes satisfactory cycle control? And even more problematic are the reliable terms. What level of avoidance is necessary for intracyclic menstrual bleeding, and is it evaluated after the first 28 day administration cycle or after prolonged use? The uncertainty

is compounded for side effects. The specification discusses various side effects ranging from headaches to cardiovascular disease. What constitutes an unacceptable avoidance of headaches is a thoroughly different question than what would constitute unacceptable avoidance of cardiovascular disease, yet the two are linked together in a single characteristic in the disputed phrase. Finally, even if the court did have individual standards against which the limitations are measured, the intrinsic record does not indicate what analytical tools or processes should be used to make the measurements.

The Supreme Court has recently held that the proper test for whether a patent is indefinite is "if its claims, read in light of the patent's specification and prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, *6 (2014). The difficulty the court has encountered in construing the terms may unavoidably present an indefinite issue that will need to be addressed at summary judgment.

Dated: October 9, 2014

UNITED STATES DISTRICT JUDGE